

### REMARKS/ARUGMENTS

Upon entry of this amendment, claims 1, 14, 15, 25, 26, 27, 30 and 33 will be amended, whereby claims 1-7, 11, 12, 14-21 and 23-36 will remain pending. Claims 1, 14, 15, 25, 26 and 33 are independent claims.

Applicants express appreciation for the withdrawal of the rejections of record, and for the reasons set forth herein respectfully submit that the newly-instituted rejections should be withdrawn.

Reconsideration and allowance of the application are respectfully requested.

#### **Rejection Of Claims Under 35 U.S.C. 112, Second Paragraph**

Claims 1-7, 11, 12, 14-21 and 24-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention.

In this ground of rejection, claims 1, 11, 14, 15, 25, 26 and 33 are asserted to be indefinite because the recitation "indocyanine green derivative" is asserted to be interpreted as having as little as one molecule in common with indocyanine green. The Examiner states that the rejection would be overcome if the claims were amended as recited in U.S. Patent No. 5,968,479, which the Examiner notes recites structures to indicate the metes and bounds of claimed compounds.

Moreover, claims 27 and 30 are rejected as being indefinite as referring to methods and compositions, respectively.

In response to these grounds of rejection, Applicants once again respectfully submit that for the reasons of record the claims pending prior to the present amendment are definite. However, in an attempt to advance prosecution of the application, the claims have been amended herein to include the fluorescent functional groups disclosed in Applicants' specification, such as beginning at page 10, as well as in U.S. Patent No. 5,968,479 and its family members JP 7-12283 and 7-223613, which family members are disclosed at page 14, first full paragraph of Applicants' specification.

Accordingly, Applicants respectfully submit that this ground of rejection should be withdrawn.

#### **Rejection Of Claims Under 35 U.S.C. 112, First Paragraph**

Claims 1-7, 11, 12, 14-21 and 24-36 are asserted to fail to comply with the written description requirements based upon the recitation of the genus "indocyanine green derivative" for similar reasons to the indefiniteness rejection.

For the reasons set forth above with respect to the indefiniteness rejection under 35 U.S.C. 1112, second paragraph, Applicants respectfully submit that the claims definitely recite Applicants' invention, whereby this ground of rejection should be withdrawn.

#### **Rejection Of Claims Under 35 U.S.C. 112, First Paragraph, As Being NonEnabled**

Claims 14-21, 23-25, 27-29 and 33-36 are asserted to be based upon a nonenabling specification. In particular, the rejection asserts that while the specification is enabling for

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methods comprising contacting the tumor cell or the malignant neoplasia of epithelial cells with an antibody that is specific for a tumor cell or a malignant neoplasia of epithelial cells, the specification does not reasonably provide enablement for methods comprising contacting the tumor cell or the malignant neoplasia of epithelial cells with any antibody. The rejection refers to page 14 of the specification, and asserts that the specification confines its teachings to examples where the antibodies used in the claimed methods are anticancer-antigen antibodies.

In contrast to the assertions in the rejection, Applicants respectfully submit that Applicants have provided sufficient guidance in the specification to enable one having ordinary skill in the art to practice Applicants' invention without undue experimentation. For example, the Examiner's attention is directed to pages 14 and 15 wherein it is indicated that these antibodies are merely examples, and that any antibodies can be used so long as they have substantial property to bind specifically to target cells or target tissues that are objects of examination and diagnosis. Therefore, Applicants' specification has provided specific examples while indicating that other antibodies can be used. Also, the claims are directed to methods using a composition containing antibody with the function of the composition being recited in the claims.

Thus, Applicants' originally filed specification, clearly discusses the broad aspects of their invention, and provides guidance as to compounds that are utilizable in connection with their invention. Moreover, the knowledge in the prior art is high with respect to compositions similar to that disclosed and claimed by Applicants. In this regard, the Examiner's attention is directed to U.S. Patent No. 5,968,479. The Examiner is reminded that the present invention is characterized to obtain a higher fluorescent intensity by using a composition comprising the diagnostic

component disclosed in U.S. Patent No. 5,968,479 as one of the components. Therefore, the property of the antibody to be used in Applicants' invention can be readily understood by one of ordinary skill in the art.

It is therefore respectfully submitted that the rejection has failed to overcome Applicants' showing of enablement and has failed to meet its burden of producing evidence or sound scientific reasoning demonstrating lack of enablement. Of course, Applicants have not disclosed working examples of every possible component that works. To do so would require that the specification include a multitude of examples. What Applicants have done, which is in accordance with the requirements of 35 U.S.C. 112, is to present the concept of their invention, which has been defined in the originally filed specification and claims, and to provide representative examples, so as to be in compliance with the best mode requirement of 35 U.S.C. 112, first paragraph.

Applicants have provided sufficient guidance for one having ordinary skill in the art to make and use Applicants' invention. Thus, without undue experimentation or effort or expense, components that are within the scope of the invention can be determined.

As stated in In re Wands, 8 U.S.P.Q.2d 1400, 1404 (CAFC 1988):

Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. "the key word is 'undue,' not 'experimentation.'"

Wands states that the factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman, 230 U.S.P.Q., at 547. In particular, it is noted that these include (1) the quantity of experimentation, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples,

(4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Weighing these factors under the present circumstances demonstrates that the 35 U.S.C. 112, first paragraph, enablement rejection is improper and should be withdrawn. In this regard, (a) the quantity of experimentation for determining if components are covered by the claims would be low following the procedures and criteria fully disclosed in Applicants' specification, (b) there is sufficient direction presented so as to ascertain by routine experimentation whether antibodies are within Applicants' claimed invention, (c) working examples are provided for a number of antibodies, and (d) the relative skill in the art, the nature of the invention, and the claim language are sufficiently related that undue experimentation would not be required so as to enable the practice of the disclosed and claimed invention for other than the specifically disclosed components.

In view of the above, the rejection under 35 U.S.C. 112, first paragraph, should be withdrawn. However, if the Examiner needs that any amendment of the claims would be beneficial, the Examiner is respectfully requested to contact the undersigned to discuss the same.

### **CONCLUSION**

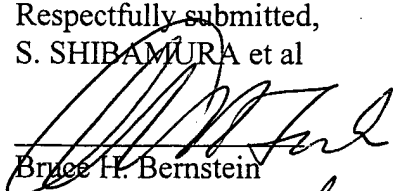
In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicant therefore respectfully requests that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

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Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,  
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